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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/19/2004

Johannes Coy

4007.008

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30448

7590

04/10/2008

AKERMAN SENTERFITT

P.O. BOX 3188

WEST PALM BEACH, FL 33402-3188

EXAMINER

AEDER, SEAN E

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/511,813	Applicant(s) COY, JOHANNES	
	Examiner SEAN E. AEDER	Art Unit 1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 March 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 34-38 and 44-50.
 Claim(s) withdrawn from consideration: 39,41-43 and 51-64.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
 13. ☐ Other: _____.

/MISOOK YU/
 Primary Examiner, Art Unit 1642

Continuation of 11. does NOT place the application in condition for allowance because: The proposed amendments and the arguments found in the Reply of 3/17/08 have been carefully considered, but are not deemed persuasive.

In regards to the rejection of claims 34-38 and 44-50 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement, Applicant argues that the instant claims differ from the claims of Eli Lilly for at least the reason that the instant claims are method claims of measuring a level of polynucleotides drawn from a single individual and any concern of genes from different species functioning in a different manner does not arise. Applicant further argues that instant claims are not directed to a construct which may not have function due to variation in sequence, but rather drawn to a method of detecting transketolase like-1 genes, which could be expected to have some amount of variation in their sequence while maintaining functionality. Applicant further states that to require independent claim 34 to recite detecting levels of "polynucleotide SEQ ID NO:1" rather than "polynucleotides that hybridize under stringent conditions to probes specific for a transketolase-like-11 gene, wherein said probes hybridize to SEQ ID NO:1 under stringent conditions" would result in a claim unnecessarily narrow in view of the disclosure set forth in the specification.

In regards to the argument that the instant claims differ from the claims of Eli Lilly for at least the reason that the instant claims are method claims of measuring a level of polynucleotides drawn from a single individual and any concern of genes from different species functioning in a different manner does not arise, a disclosure that does not adequately describe a product itself cannot adequately describe a method of detecting said product. Further, the arguments based on Eli Lilly are not based on whether genes from different species function in a different manner. Rather, the arguments based on Eli Lilly are based on the argument that a description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features that are common to the genus that "constitute a substantial portion of the genus". The specification does not disclose a representative number of polynucleotides that hybridize under stringent conditions to probes specific for a transketolase like-1 gene wherein said probes hybridize under stringent conditions to SEQ ID NO:1. Further, the specification does not disclose any identifying structural feature that is common to the genus. Further, it is noted that the instant claims do not require said probes to be used when performing the claimed method.

In regards to the argument that instant claims are not directed to a construct which may not have function due to variation in sequence, but rather drawn to a method of detecting transketolase like-1 genes, which could be expected to have some amount of variation in their sequence while maintaining functionality, Applicant is arguing limitations not recited in the claims. The claims are not drawn to detecting transketolase like-1 genes. Rather, the claims are drawn to detecting any polynucleotide that hybridizes under stringent conditions to probes specific for transketolase like-1 gene, wherein said probes hybridize under stringent conditions to SEQ ID NO:1. Again, it is noted that the instant claims do not require said probes to be used when performing the claimed method.

In regards to the statement that to require independent claim 34 to recite detecting levels of "polynucleotide SEQ ID NO:1" rather than "polynucleotides that hybridize under stringent conditions to probes specific for a transketolase-like-11 gene, wherein said probes hybridize to SEQ ID NO:1 under stringent conditions" would result in a claim unnecessarily narrow in view of the disclosure set forth in the specification, Applicant does not have a written description of methods of "polynucleotides that hybridize under stringent conditions to probes specific for a transketolase-like-11 gene, wherein said probes hybridize to SEQ ID NO:1 under stringent conditions" for the reasons discussed above and in previous Office Actions.

In regards to the rejection of claims 34-38 and 44-50 under 35 U.S.C. 112, first paragraph, for failing to comply with the enablement requirement, Applicant argues that there are hybridization conditions in which particular probes specific for transketolase like-1 gene would not hybridize to TKT sequences or TKTL2 sequences. Applicant further argues that transketolase like-1 transcripts can be discriminated from TKT and TKTL2 transcripts based on transcript size. Applicant further argues that the Examiner does not point out a specific passage indicating that transketolase like-1, TKT, and TKTL2 transcripts would hybridize to each others' complements.

In regards to the argument that there are hybridization conditions in which particular probes specific for transketolase like-1 gene would not hybridize to TKT sequences or TKTL2 sequences, Applicant is arguing limitations not recited in the claims. The claims do not require that probes used in the claimed method are specific for transketolase like-1 gene and would not hybridize to TKT sequences or TKTL2 sequences.

In regards to the argument that transketolase like-1 transcripts can be discriminated from TKT and TKTL2 transcripts based on transcript size, Applicant is arguing limitations not recited in the claims. The instant claims do not require one to discriminate transketolase like-1 transcripts from TKT and TKTL2 transcripts. Further, the claims are not limited to detecting transketolase like-1 genes. Rather, the claims are drawn to detecting any polynucleotide that hybridizes under stringent conditions to probes specific for transketolase like-1 gene, wherein said probes hybridize under stringent conditions to SEQ ID NO:1. Again, it is noted that the instant claims do not require said probes to be used when performing the claimed method.

In regards to the argument that the Examiner does not point out a specific passage indicating that transketolase like-1, TKT, and TKTL2 transcripts would hybridize to each others' complements, Applicant is directed to lines 11-26 of the instant specification. The instant specification discloses that "transketolase like-1" polynucleotides encompass variants with any number of substitutions, additions, deletions and/or insertions. Due to the broad definition of "transketolase like-1", allowing any amount of variation, one of skill in the art would recognize that the instant specification supports the assertion that transketolase like-1, TKT, and TKTL2 transcripts would hybridize to each others' complements.

